

APR 17 2003

**510(K) SUMMARY OF SAFETY AND EFFECTIVENESS**

**Name of Firm:** Blackstone Medical, Inc.  
90 Brookdale Drive  
Springfield, MA 01104

**510(k) Contact:** Dean E. Ciporkin  
Director, Regulatory Affairs and Quality Assurance

**Trade Name:** Blackstone™ Spinal Fixation System  
Rigid Cross Connector

**Common Name:** Rod and screw spinal instrumentation

**Device Product Code  
& Classification:** MNH – 888.3070 – Spondylolisthesis Spinal Fixation  
Device System  
KWQ - 888.3060 - Spinal Intervertebral Body Fixation  
Orthosis  
MNI – 888.3070 – Pedicle Screw Spinal System

**Substantially  
Equivalent Device:** Blackstone™ Spinal Fixation System (K994217)  
Blackstone™ Spinal Fixation System Second Generation Cross  
Connector (K003735)

**Device Description:**

The Blackstone Spinal Fixation System is a titanium alloy (6AL-4V ELI, per ASTM F136) device comprised of a variety of non-sterile, single use components. The Blackstone Spinal Fixation System Rigid Cross Connector is a modification to the Spinal Fixation System, which allows a surgeon to build a spinal implant construct. The system is attached to the vertebral body by means of screws to the non-cervical spine.

The Blackstone Spinal Fixation System consists of an assortment of screws, hooks, rods, and cross connectors that have received 510(k) clearance (K994217, K013558, K013885, K020674, K023498, K003537).

**Intended Use / Indications for Use:**

The Blackstone Spinal Fixation System is intended for non-cervical use in the spine. The Blackstone Spinal Fixation System, when used for pedicle screw fixation, is intended only for patients:

- a) Having severe spondylolisthesis (Grades 3 and 4) at the L5-S1 joint;
- b) Who are receiving fusion using autogenous bone graft only;
- c) Who are having the device fixed or attached to the lumbar and sacral spine (L3 and below); and
- d) Who are having the device removed after the development of a solid fusion mass.

The Blackstone Spinal Fixation System, when used as a pedicle screw system in skeletally mature patients, is intended to provide immobilization and stabilization of spinal segments, as an adjunct to fusion, in treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine:

- a) Degenerative spondylolisthesis with objective evidence of neurologic impairment;
- b) Fracture;
- c) Dislocation;
- d) Scoliosis;
- e) Kyphosis;
- f) Spinal tumor;
- g) Previous failed fusion (pseudarthrosis).

The Blackstone Spinal Fixation System, when used for anterolateral non-pedicle screw fixation to the non-cervical spine, is intended for the following indications:

- a) Degenerative disc disease (as defined as back pain of discogenic origin with degenerative disc confirmed by history and radiographic studies);
- b) Spinal stenosis;
- c) Spondylolisthesis;
- d) Spinal deformities (i.e., scoliosis, kyphosis, lordosis);
- e) Pseudoarthrosis;
- f) Tumor;
- g) Trauma (i.e., fracture or dislocation).
- h) Previous failed fusion.

The Blackstone Spinal Fixation System, when used for posterior non-pedicle screw fixation to the non-cervical spine, is intended for the following indications:

- a) Degenerative disc disease (defined as back pain of discogenic origin with degenerative disc confirmed by patient history and radiographic studies);
- b) Spinal stenosis;
- c) Spondylolisthesis;
- d) Spinal deformities (i.e., scoliosis, kyphosis and/or lordosis);
- e) Pseudoarthrosis;
- f) Tumor;
- g) Trauma (i.e., fracture or dislocation);
- h) Previous failed fusion.

Premarket Notification Special 510(k)

Blackstone Medical, Inc.

*Blackstone™ Spinal Fixation System*

*Rigid Cross Connector (System Modification)*

**Confidential**

**BASIS OF SUBSTANTIAL EQUIVALENCE:**

The Blackstone Rigid Cross Connector, by its very nature, is substantially equivalent to the Blackstone Spinal Fixation System (K994217, K003735), which has been cleared by the FDA for certain anterior and pedicle fixation indications.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

APR 17 2003

Mr. Dean E. Ciporkin  
Director, Regulatory Affairs and Quality Assurance  
Blackstone Medical, Inc.  
90 Brookdale Drive  
Springfield, Massachusetts 01104

Re: K030862

Trade Name: Blackstone™ Spinal Fixation System – Rigid Cross Connector  
Regulation Number: 21 CFR 888.3070, 888.3060, 888.3050  
Regulation Name: Pedicle screw spinal system, Spinal intervertebral body fixation  
orthosis, Spinal interlaminar fixation orthosis  
Regulatory Class: II  
Product Code: MNI, MNH, KWQ, KWP  
Dated: March 14, 2003  
Received: March 18, 2003

Dear Mr. Ciporkin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

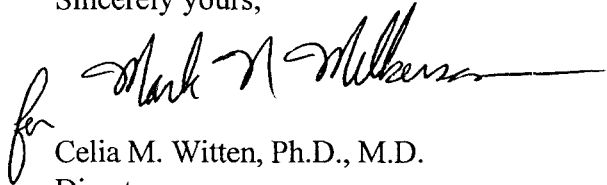
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,

for

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative  
and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Premarket Notification Special 510(k)  
Blackstone Medical, Inc.  
*Blackstone™ Spinal Fixation System*  
*Rigid Cross Connector (System Modification)*  
**Confidential**

510(k) Number: K030862

**Device Name:** *Blackstone™ Spinal Fixation System*

**Indications for Use:**

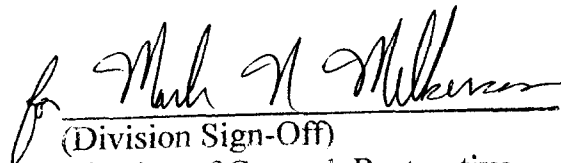
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- b) Fracture;
- c) Dislocation;
- d) Scoliosis;
- e) Kyphosis;
- f) Spinal tumor;
- g) Failed previous fusion (pseudarthrosis).



(Division Sign-Off)  
Division of General, Restorative  
and Neurological Devices

510(k) Number K030862

The Blackstone Spinal Fixation System, when used for anterolateral non-pedicle screw fixation to the non-cervical spine, is intended for the following indications:

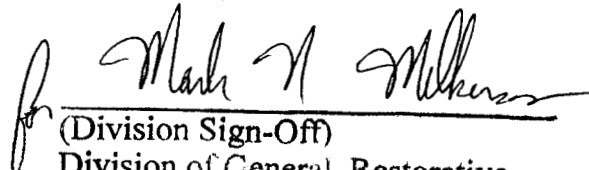
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- d) Spinal deformities (i.e., scoliosis, kyphosis, lordosis);
- e) Pseudoarthrosis;
- f) Tumor;
- g) Trauma (i.e., fracture or dislocation).
- h) Failed previous fusion.

The Blackstone Spinal Fixation System, when used for posterior non-pedicle screw fixation to the non-cervical spine, is intended for the following indications:

- a) Degenerative disc disease (defined as back pain of discogenic origin with degenerative disc confirmed by patient history and radiographic studies);
- b) Spinal stenosis;
- c) Spondylolisthesis;
- d) Spinal deformities (i.e., scoliosis, kyphosis and/or lordosis);
- e) Pseudoarthrosis;
- f) Tumor;
- g) Trauma (i.e., fracture or dislocation);
- h) Failed previous fusion.

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Concurrence of CDRH, Office of Device Evaluation

  
(Division Sign-Off)  
Division of General, Restorative  
and Neurological Devices

510(k) Number K 030862

Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_